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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,447	02/06/2002	Kurt R. Gehlsen	MAXIM.073DV1C1	1030
20995	7590	09/09/2004	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			BERKO, RETFORD O	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/068,447

Applicant(s)

GEHLSSEN, KURT R.

Examiner

Relford Berko

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 26-32 and 34-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-32 and 34-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

**Acknowledgement:** Applicant's amendment filed April 12, 2004 is acknowledged.

#### **Status of Claims**

The status of the claims is as follows:

Claims 26-41 are pending following the amendment.

Claims 42, 43 and 44 were new claims added by the amendment.

Claim 33 was cancelled in view of the amendment.

#### **Correction of Error:**

In the previous office action, Examiner erroneously referred to Patent WO 95/23601 as Bruce et al. For the record, a correction is hereby made: the reference is properly referred to as Jack et al (i.e. Patent WO '601).

#### **Claim Rejections-35 U.S.C. 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 26-32 and 35-37 are rejected under 35 USC 102(b) as anticipated by Hellstrand et al (WO 97/42968).

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The claims are directed toward a method of making a cosmetic composition for topically delivering a compound that inhibits production of reactive oxygen metabolites (ROMs); comprising providing a cosmetically acceptable carrier and a compound selected from a group consisting of histamine or histamine salts. The claims are also directed toward the method wherein the compound inhibits production of ROMs, and the histamine releasing compound is retinoic acid, IL-3; allergen and wherein the method produces a composition that is a lipstick, a shampoo or a spray. The claims are also drawn toward the composition formed by the method wherein said composition has a cosmetic carrier and the compound is a histamine or its salt

As in claim 26, Hellstrand et al (Patent WO '968) teaches a method for obtaining a composition containing histamine salts; said composition comprises a carrier and the composition is in transdermal formulation (abstract, page 6, lin 30-35 and page 20, lin 15-20).

As in claim 27-37, the substance produced by the method results in the release of higher endogenous histamine (page 15, lin 12; page 13, lin 14 and 20, lin 35); the endogenous releasing compound is retinoic acid or IL-3 or allergens and the composition formed is a gel (a shampoo; page 20, lin 20-25).

Claims 26-32 and 27-37 are anticipated by Patent WO '968.

2. Claims 26, 29 and 34 are rejected under 35 USC 102(b) as anticipated by Jack et al (WO 95/23601).

The claims are directed toward a method of making a cosmetic composition for topically delivering a compound that inhibits production of reactive oxygen metabolites (ROMs); comprising providing a cosmetically acceptable carrier and a compound selected from a group consisting of histamine or histamine salts. The claims are also directed toward the method

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wherein the compound inhibits production of ROMs, and the histamine releasing compound is retinoic acid, IL-3; allergen and wherein the method produces a composition that is a lipstick, a shampoo or a spray. The claims are also drawn toward the composition formed by the method wherein said composition has a cosmetic carrier and the compound is a histamine or its salt

WO '601 teaches applicant's claim 26 in that it teaches a method and composition for topical treatment of damaged tissue using histamine as active ingredient (abstract, page 2, lin 1 and page 71, lin 1-20).

WO teaches applicant's claims 29 and 34-- the Patent teaches histamine phosphate in a medication for topical treatment of sunburn as well as for the treatment of other skin conditions (page 71, lin 51).

Claims 26, 29 and 34 are anticipated by WO '601.

### **Claim Rejections-35 USC 103**

#### **New Ground of Rejection:**

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 26-32, 34-42 and claim 44 are rejected under 35 USC 103(a) as being unpatentable over Hellstrand et al (WO 97/42968) in view of Bruce et al (WO '95/23601) further in view of Bathurst et al (US6, 004, 579; 102(e) date of Sep 4, 1997).

The claims are directed toward a method of making a cosmetic composition for topically delivering a compound that inhibits production of reactive oxygen metabolites (ROMs); comprising providing a cosmetically acceptable carrier and a compound selected from a group consisting of histamine or histamine salts. The claims are also directed toward the method wherein the compound inhibits production of ROMs, and the histamine releasing compound is retinoic acid, IL-3; allergen and wherein the method produces a composition that is a lipstick, a shampoo or a spray. The claims are further drawn toward the composition formed by the method wherein said composition has a cosmetic carrier and the compound is a histamine or its salt, that the composition comprises of colorant (FDA red dye or Yellow No. 5); contains a fragrance; moisturizer and sunscreen and soap.

Hellstrand et al (Patent WO '968) and Bruce (Patent WO '601) have been discussed. Neither patent discloses a method for making the composition wherein histamine phosphate is the active ingredient and is also formulated to contain fragrance and colorants.

Bathurst (Patent '579) disclose a method of making topical composition for treatment of dermatological conditions; said composition formulated as liquids, creams, lotion, ointment, suntan lotion, sunscreen et and (col 10, lin 60-65, continuing to col 11, lin 1-10). According to

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the disclosure in Patent '579, the formulations are for treating dermatologic conditions (col 14, lin 55-60 and col 19, lin 10-14).

One of ordinary skill in the art would be motivated to make a dermatologic composition for topical application as disclosed in the cited prior art and include cosmetically acceptable carrier and ingredients as fragrances and colorants. One of ordinary skill would expect to obtain a cosmetic composition such as creams, gels, lotions and sunscreens that upon topical application allow the skin to heal and resist cell damage as well as restore normal skin function. The motivation to combine the references cited lies in the reasonable expectation for success in achieving the beneficial effects of the composition in treating various dermatological conditions as disclosed by Bathurst et al in Patent '579 (col 14, lin 42-60). Therefore the invention as a whole would have been prima facie obvious to one of ordinary skill at the time it was made.

### ***Response To Arguments***

Applicant's arguments filed March 11, 2004 in regards to the 35 USC 102 (b) rejections have been fully considered but they are found not persuasive.

Applicant argue that independent claims 26 and 34 are directed only to a cosmetic composition and the use of such cosmetic composition wherein the claimed composition comprise effective dose of histamine or histamine related compound that inhibits the production and release of ROMs in a cosmetically accepted carrier adapted for topical delivery as a cosmetic product and that Patent WO 968 only teaches a pharmaceutical composition; said composition and the methods disclosed in Patent 968 involve systemic administration of histamine.

In response to this argument, the examiner points out that the biochemical effect of the composition in increasing endogenous histamine; i.e.local or systemic is the critical issue and

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unless a criticality is shown, a pharmaceutically acceptable carrier or a cosmetically acceptable carrier would be just as effective because it is a composition. Furthermore, giving the broadest interpretation to the claims, Patent WO '968 discloses methods for obtaining the composition; said composition is in the form of a gel and the gel can be applied topically to treat dermatological conditions including photodermatitis and thermal burns and is therefore a cosmetically applied (page 20, lin 15-20 at claim 7).

Applicant argues that neither Patent WO '968 nor Patent WO '601 disclose a cosmetic composition comprising effective dose of histamine-related compound that inhibits the production and release of ROMs in a cosmetically acceptable carrier adapted for topical delivery as a cosmetic product

In response, applicant's argument respecting Patent WO '968 has been discussed above. Respecting Patent WO '601, the patent discloses composition for topical treatment of lesions (pages 71-73).

Applicant argues that WO '968 speaks to systemic administration of histamine in order to establish stable levels of histamine in the blood but in contrast, the instant claims are directed toward topical delivery of the claimed compounds.

In response, WO '968 also discloses the transdermal delivery of the composition comprising histamine compounds (page 6, lin 30-35; page 13, lin 1-5 and page 18, lin8 and 30-35).

### **Correspondence**



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Retford Berko** whose telephone number is 571-272-0590. The examiner can normally be reached on M-F from 8.00 am to 5.30 pm

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Thurman K Page**, can be reached on 571-272-0602.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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